K090767

SECTION 5 **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**
Special 510(k)

JUN 11 2009

SUBMITTER INFORMATION

Company Name:	Interventional Spine, Inc
Company Address:	13700 Alton Parkway Suite 160 Irvine, CA 92618
Company Phone:	(949) 472-0006
Company Facsimile:	(949) 472-0016
Contact Person:	Carol Emerson

DEVICE IDENTIFICATION

Trade Name:	PERPOS™ FCD-2 System, Single Patient Use PERPOS™ FCD-2 Implant, ANCHOR AND STABILIZER
Common Name:	Facet Screw and associated manual surgical instruments
Classification Name:	Unclassified, various manual surgical instruments
Product Code:	MRW
Device Panel:	Orthopedic, General, and Plastic Surgery
Device Class:	Unclassified

PREDICATE DEVICES

PERPOS™ PLS System previously cleared under 510(k) K082795

DEVICE DESCRIPTION

The PERPOS™ FCD-2 Single Use System consists of two each of a double-helix facet screw with a compression-locking collar, retaining ring and a self-retaining polymer washer packaged in a single use tray with the associated manual instruments. Modifications from the predicate device include changes to the washer configuration, instrumentation and packaging.

INTENDED USE/INDICATIONS for USE

The PERPOS™ FCD-2 System isindicated for spondylolisthesis, spondylolysis, degenerative disc disease (DDD) as defined by back pain of discogenic origin as confirmed by rediographic studies, degeneration of the facets with instability and fracture, pseudoarthrosis, or failed previous fusion.

The intended use of the PERPOS™ FCD-2 Anchor and Stabilizer is to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The PERPOS™ FCD-2 may be used to supplement legally marketed anterior fusion products in order to create an anterior/posterior fixation construction as an aid to fusion. The PERPOS FCD-2 is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels from L1-S1. The intended use of the associated manual surgical instruments is to aid in the implantation of the PERPOS™ FCD-2 Anchor and Stabilizer.

TECHNOLOGICAL CHARACTERISTICS and SUBSTANTIAL EQUIVALENCE

Documentation was provided to demonstrate that the PERPOS™ FCD-2 System is identical or similar to the predicate device in technological characteristics. The PERPOS™ FCD-2 System is identical to the predicate device in intended use and identical or substantially equivalent to the predicate device in materials, design and technological characteristics.

PERFORMANCE TESTING

Risk analysis was conducted on the impact of the changes and appropriate design verification and validation was conducted under the company's design controls.

CONCLUSION

The results from design controls and the information provided in this submission support the conclusion that the PERPOS™ FCD-2 System is substantially equivalent to the predicate, PERPOS™ PLS System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2009

Interventional Spine, Incorporated
% Ms. Carol Emerson
VP, Quality and Logistics
13700 Alton Parkway, Suite 160
Irvine, California 92618

Re: K090767
Trade/Device Name: PerPos FCD-2 System
Regulatory Name/Number: Unclassified
Regulatory Class: Unclassified
Product Code: MRW
Dated: May 4, 2009
Received: May 12, 2009

Dear Ms. Emerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman for

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090767

Device Name: Single Use PERPOS™ FCD-2 System

Indications For Use:

The PERPOS™ FCD-2 is indicated for spondylolisthesis, spondylolysis, degenerative disc disease (DDD) as defined by back pain of discogenic origin as confirmed by radiographic studies, degeneration of the facets with instability and fracture, pseudoarthrosis, or failed previous fusion.

The intended use of the PERPOS™ FCD-2 is to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The PERPOS FCD-2 may be used to supplement legally marketed anterior fusion products in order to create an anterior/posterior fixation construction as an aid to fusion. The screws are inserted posteriorly through the superior side of the facet, across the facet joint and into the pedicle. The PERPOS™ FCD-2 is intended for lumbar bilateral facet fixation, with bone graft, at single or multiple levels from L1 to S1. The intended use of the associated manual surgical instruments is to aid in the implantation of the PERPOS™ FCD-2 Anchor and Stabilizer.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090767